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C912 U.S. PTO

**UTILITY PATENT APPLICATION TRANSMITTAL
(Small Entity)***(Only for new nonprovisional applications under 37 CFR 1.53(b))*Docket No.
ML-0414DIV

Total Pages in this Submission

49

JC682 U.S. PTO

09/11/00

09/11/00

TO THE ASSISTANT COMMISSIONER FOR PATENTS**Box Patent Application
Washington, D.C. 20231**

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled:

SYSTEM FOR CONFOCAL IMAGING WITHIN DERMAL TISSUE

and invented by:

James M. Zavislan

If a CONTINUATION APPLICATION, check appropriate box and supply the requisite information:

☐ Continuation ☒ Divisional ☐ Continuation-in-part (CIP) of prior application No.: 08/942,431

Which claims the benefit of U.S. Provisional Appln. No. 60/028,847, filed

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.: 10/18/96

Which is a:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.:

Enclosed are:

Application Elements

1. ☒ Filing fee as calculated and transmitted as described below
2. ☒ Specification having 20 pages and including the following:
 - a. ☒ Descriptive Title of the Invention
 - b. ☒ Cross References to Related Applications (if applicable)
 - c. ☐ Statement Regarding Federally-sponsored Research/Development (if applicable)
 - d. ☐ Reference to Microfiche Appendix (if applicable)
 - e. ☒ Background of the Invention
 - f. ☒ Brief Summary of the Invention
 - g. ☒ Brief Description of the Drawings (if drawings filed)
 - h. ☒ Detailed Description
 - i. ☒ Claim(s) as Classified Below
 - j. ☒ Abstract of the Disclosure

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(Small Entity)

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Application Elements (Continued)

3. ☒ Drawing(s) *(when necessary as prescribed by 35 USC 113)*

a. ☐ Formal b. ☒ Informal Number of Sheets 11

4. ☒ Oath or Declaration

a. ☐ Newly executed *(original or copy)* ☐ Unexecuted

b. ☒ Copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional application only)*

c. ☒ With Power of Attorney ☐ Without Power of Attorney

d. ☐ DELETION OF INVENTOR(S)

Signed statement attached deleting inventor(s) named in the prior application,
see 37 C.F.R. 1.63(d)(2) and 1.33(b).

5. ☒ Incorporation By Reference *(usable if Box 4b is checked)*

The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied
under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby
incorporated by reference therein.

6. ☐ Computer Program in Microfiche

7. ☐ Genetic Sequence Submission *(if applicable, all must be included)*

a. ☐ Paper Copy

b. ☐ Computer Readable Copy

c. ☐ Statement Verifying Identical Paper and Computer Readable Copy

Accompanying Application Parts

8. ☒ Assignment Papers *(cover sheet & documents)* (copy from prior application)

9. ☐ 37 CFR 3.73(b) Statement *(when there is an assignee)*

10. ☐ English Translation Document *(if applicable)*

11. ☐ Information Disclosure Statement/PTO-1449 ☐ Copies of IDS Citations

12. ☒ Preliminary Amendment

13. ☒ Acknowledgment postcard

14. ☒ Certificate of Mailing

☐ First Class ☒ Express Mail *(Specify Label No.):* EL641552591US

UTILITY PATENT APPLICATION TRANSMITTAL
(Small Entity)

(Only for new nonprovisional applications under 37 CFR 1.53(b))

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Accompanying Application Parts (Continued)

15. ☐ Certified Copy of Priority Document(s) (if foreign priority is claimed)
16. ☒ Small Entity Statement(s) - Specify Number of Statements Submitted: 1, copy from prior app.
17. ☐ Additional Enclosures (please identify below):

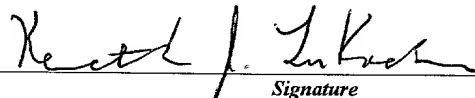
Fee Calculation and Transmittal

CLAIMS AS FILED

For	#Filed	#Allowed	#Extra	Rate	Fee
Total Claims	25	- 20 =	5	x \$9.00	\$45.00
Indep. Claims	4	- 3 =	1	x \$39.00	\$39.00
Multiple Dependent Claims (check if applicable) <input type="checkbox"/>					\$0.00
BASIC FEE					\$345.00
OTHER FEE (specify purpose)					\$0.00
TOTAL FILING FEE					\$429.00

- ☒ A check in the amount of \$429.00 to cover the filing fee is enclosed.
- ☒ The Commissioner is hereby authorized to charge and credit Deposit Account No. 50-1101 as described below. A duplicate copy of this sheet is enclosed.
- ☐ Charge the amount of as filing fee.
- ☒ Credit any overpayment.
- ☒ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
- ☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).

Dated: September 11, 2000


Signature

Kenneth J. LuKacher
Attorney for Applicant
Registration No, 38,539
South Winton Court
3136 Winton Road South, Suite 304
Rochester, New York 14623
Telephone: (716) 424-2670

KJL/tsm
CC:

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY
STATUS (37 CFR 1.9(f) AND 1.27 (c)) - SMALL BUSINESS CONCERN**

Docket No.
ML-0414CV

Serial No.

N/A

Filing Date

Concurrently herewith

Patent No.

N/A

Issue Date

N/A

Applicant/ **Zavislan, James M.**
Patentee:

Invention: **SYSTEM FOR CONFOCAL IMAGING WITHIN DERMAL TISSUE**

I hereby declare that I am:

- ☐ the owner of the small business concern identified below:
☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF CONCERN: Lucid Technologies, Inc.

ADDRESS OF CONCERN: 235 Middle Rd, Henrietta, NY 14467

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 37 CFR 121.3-18, and reproduced in 37 CFR 1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the above identified invention described in:

- ☒ the specification filed herewith with title as listed above.
☐ the application identified above.
☐ the patent identified above.

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed on the next page and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 CFR 1.9(c) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☒ no such person, concern or organization exists.
☐ each such person, concern or organization is listed below.

FULL NAME _____
 ADDRESS _____

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME _____
 ADDRESS _____

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME _____
 ADDRESS _____

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME _____
 ADDRESS _____

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING: James M. Zavislan

TITLE OF PERSON SIGNING _____

OTHER THAN OWNER: Vice President

ADDRESS OF PERSON SIGNING: 5 Wandering Trail
Pittsford, New York

SIGNATURE: _____

James M. Zavislan

DATE: _____

9/24/97

CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)Applicant(s): **James M. Zavislan**

Docket No.

ML-0414DIV

Serial No.

N/A

Filing Date

Concurrently herewith

Examiner

N/A

Group Art Unit

N/A

Invention: **SYSTEM FOR CONFOCAL IMAGING WITHIN DERMAL TISSUE**

I hereby certify that the following correspondence:

DIVISIONAL PATENT APPLICATION*(Identify type of correspondence)*

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under

37 CFR 1.10 in an envelope addressed to: The Assistant Commissioner for Patents, Washington, D.C. 20231

September 11, 2000*(Date)***Tammy S. Moynihan***(Typed or Printed Name of Person Mailing Correspondence)**(Signature of Person Mailing Correspondence)***EL641552591US***("Express Mail" Mailing Label Number)*

Note: Each paper must have its own certificate of mailing.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Zavislan
Application No: Divisional of USSN 08/942,431, filed October 1, 1997
Filed: Concurrently herewith
Title: SYSTEM FOR CONFOCAL IMAGING WITHIN DERMAL TISSUE
Examiner: Casler, B. Art Unit: 3737
Attorney Docket: ML-0414CV

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Please amend the above-identified application as follows:

In the Specification

Page 1, line 5, after "application" insert -- is a divisional of U.S. Patent Application No. 08/942,431, filed October 1, 1997, which --.

Page 5, line 24, replace "5/20/96" with -- May 20, 1996, now U.S. Patent No. 5,788,639, issued August 4, 1998, --;

Page 8, line 23, before "objective" insert -- the --, and delete "35";

Page 8, line 23, replace "5/20/96" with -- May 20, 1996, now U.S. Patent No. 5,788,639, issued August 4, 1998, --;

Page 10, line 16, replace "60" with -- 82 --, and replace "35" with -- 83 --;

Page 10, line 17, after "1996" insert --, now U.S. Patent No. 5,788,639, issued August 4, 1998, --.

In the Claims

Please cancel Claims 9-18, 24 and 25.

Claim 23, line 3, after "means" insert --, -- and after "platen" insert --, --.

Please rewrite Claims 1 and 26 as follows:

1. (amended) A system for dermatological examination of the skin tissue of a patient comprising:

means for maintaining an area of the skin tissue under stress by application of force [at the edges of said area]; and

an imaging head₁ coupled to said maintaining means, [for] capable of imaging a section of said stressed skin tissue to provide therewith an integrated assembly.

26. (amended) A system for examining [the] tissue [of a patient] comprising:

means for maintaining an area of the tissue under stress by application of force upon said tissue [at the edges of said area]; and

an imaging head₁ coupled to said maintaining means, capable of [for] imaging said stressed tissue from light returned from a scanned focal spot through said tissue to provide an image of a section [therewith an integrated assembly].

Please insert the following new Claims 27-37 as follows:

27. The system according to Claim 1 wherein said maintaining means comprises a platen having means through which said tissue is imaged by said imaging head.

28. The system according to Claim 27 wherein said platen is positionable with respect to said tissue.

29. The system according to Claim 1 further comprising means for fixing the position of said maintaining means with respect to said patient.

30. The system according to Claim 1 wherein said imaging head is movable with respect to said maintaining means to position said imaging head with respect to said stressed tissue.

31. The system according to Claim 1 wherein said maintaining means applies force against at least the edges of said area of the skin tissue.

32. The system according to Claim 26 wherein said tissue represents one of skin tissue and internal tissue.

33. The system according to Claim 26 wherein said maintaining means applies force against at least the edges of said area of the tissue.

34. The system according to Claim 26 wherein said imaging head is movable with respect to said maintaining means to position said imaging head with respect to said stressed tissue.

35. A method for examination of tissue comprising the steps of:
 providing a platen having an opening;
 maintaining an area of the tissue under stress by application of said platen upon said tissue; and
 imaging said stressed tissue through said opening of said platen.

36. The method according to Claim 35 further comprising the step of:
 positioning said platen with respect to the area of the tissue to be imaged.

37. The method according to Claim 35 wherein said opening of said platen has a material window.

Remarks

Amendments to the Specification after page 1 are the same as amendments made to Parent Application Serial Number 08/942,431.

Claims 9-18, 24 and 25 are cancelled, and Claims 27-37 have been added for consideration by the Examiner.

Dated: 9/11/00

Respectfully submitted,



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SYSTEM FOR CONFOCAL IMAGING WITHIN DERMAL TISSUE

Abstract

5 An improved system for confocal imaging within dermal tissue of a patient is provided which minimizes instability in confocal images by reducing the relative motion of the tissue with respect to the confocal imaging optics of the system. The system includes a mechanism for maintaining an area of skin tissue under stress by application of force at the edges of the area, and an imaging head coupled to this mechanism for imaging the stressed skin. The
10 mechanism includes a mechanical structure, such as a platen, brace, or attachment, which both supports the imaging head of the system and applies stress to a limited surface area of the tissue to minimize skin motion during confocal imaging.

SYSTEM FOR CONFOCAL IMAGING WITHIN DERMAL TISSUE

Description

5 This application claims the benefit of priority from co-pending U.S. Provisional Application Serial No. 60/028,847, filed October 18, 1996.

Field of the Invention

10 The present invention relates to a confocal imaging system for in vivo clinical examinations of dermal and subdermal tissues, and particularly to a confocal imaging system of a patient's skin tissue which minimizes instability in confocal images by reducing the relative motion of the tissue with respect to the confocal imaging optics of the system. This invention is especially suitable for providing an instrument or attachment for dermal pathological applications.

Background of the Invention

15 Systems have been proposed for confocal scanning of skin, such as described in Rajadhyaksha et al., "In vivo Confocal Scanning Laser Microscopy of Human Skin: Melanin provides strong contrast." The Journal of Investigative Dermatology, Volume 104, No. 6, 20 June 1995, pages 1-7. These systems have confocal optics which direct light to the patient's skin tissue and image the returned reflected light. Such optics have a limited field of view of the patient's skin tissue, which for example may cover a tissue area less than one millimeter wide. One problem with these systems is that motion of the patient during confocal imaging can cause the tissue area being imaged to move relative to the system's confocal optics, 25 shifting the field of view of the tissue area with respect to the optics. Consequently, confocal images from such systems may appear unstable to the viewing physician, making it difficult for the physician to observe dermal structures of interest. Even slight motion of the patient's skin tissue, such as due to involuntary muscle movement in adjacent tissue or from a

circulatory pulse, can cause dermal structures of a confocal image to appear to move in and out of the imaged tissue area.

Summary of the Invention

5 Accordingly, it is the principal object of the present invention to provide an improved system for confocal imaging within dermal and subdermal tissue of a patient which minimizes instability in confocal images by reducing the relative motion of the tissue with respect to the confocal imaging optics of the system.

10 It is another object of the present invention to provide an improved system for confocal imaging of tissue having a mechanical structure, such as a platen, brace, or attachment which both supports the confocal imaging optics of the system and applies stress to a limited surface area of the tissue to minimize skin motion during confocal imaging.

15 Briefly described, the system embodying the present invention includes a mechanism for maintaining an area of skin tissue under stress by application of force at the edges of the area, and an imaging head coupled to this mechanism for imaging the stressed skin. The mechanism and imaging head provide an integrated assembly. In one embodiment, the mechanism of the system for maintaining an area of skin tissue under stress is provided by a platen, which is positionable with respect to the patient having the skin tissue to be examined. The imaging head is coupled to the platen and is positioned for imaging through an
20 orifice in the platen. To position the platen with respect to the patient, the patient is supported by a table and the platen rides in a carriage upon rails over the patient. The carriage and platen assembly may be temporarily locked in position upon the rails. Another mechanism is provided in the system for moving the platen from an up position in the carriage, where the platen is spaced from the patient, to a down position onto the surface of the skin tissue of the
25 patient, such that in the down position the force of the platen stresses the skin tissue within the orifice of the platen.

In a second embodiment, the mechanism of the system for maintaining an area of skin tissue under stress is provided by a brace supporting the imaging head. The brace has an opening through which the imaging head images the skin tissue. The brace is restrained by straps to the body part of the patient having the skin tissue in order to force the brace against the skin tissue, thereby stressing the skin tissue within the opening of the brace. The brace may further include an upper lamination, coupled to the imaging head, and a lower lamination, coupled to the restraining straps, which provides the opening of the brace. The lower lamination has slots for receiving the upper lamination in which the upper lamination is movable within the slots over the lower lamination and temporarily fixable within respect to the lower lamination. The upper lamination has an aperture (or window) substantially smaller than the opening in the lower lamination. Through the aperture of the upper lamination, the imaging head images the stressed skin tissue within the opening of the lower lamination.

In a third embodiment, the mechanism of the system for maintaining an area of skin tissue under stress is provided by an attachment having an inner window member and a flexible diaphragm member extending radially from the inner member. A suction mechanism is provided for creating a vacuum between the attachment and the surface of the skin tissue to force the skin tissue against the inner member, thereby stressing the skin tissue adjacent to the inner member. The imaging head images the stressed skin tissue through the window member. The diaphragm member may further include a semi-rigid ring along its outer periphery and an annular protruding section which defines inner and outer cavities when the attachment is adjacent to the skin tissue. The suction mechanism may then selectively create suction in the inner and outer cavities, when the attachment is adjacent to the skin tissue, to pull the skin tissue into the cavities and stress the skin tissue adjacent to the inner member.

The three embodiments of the system are particularly suitable for imaging external tissue in different regions of the patient's body. The platen may be used for confocal imaging of skin tissue on the chest or back. The brace may be used for gross anatomical features, such as the arm, leg or torso, around which the straps can hold the brace upon. The attachment is

useful for smaller regions of the skin, where there is no gross anatomical feature, or where the surface of the skin tissue is not substantially level.

Brief Description of the Drawings

5 The foregoing objects, features and advantages of the invention will become more apparent from a reading of the following description in connection with the accompanying drawings in which:

FIG. 1 is a side view of the system in accordance with a first embodiment of the present invention having the platen of the system in a down position;

10 FIG. 2 is a plan view of the system of FIG. 1;

FIG. 3 is a front view of the system of FIG. 1 without the subject patient;

FIG. 4 is a perspective view of the platen of the system of FIG. 1;

FIG. 5 is a side view of the system in accordance with a second embodiment of the present invention;

15 FIG. 6 is a front view of the system of FIG. 5 without the subject skin tissue;

FIG. 7 is a plan view of the system of FIG. 5 without the subject skin tissue;

FIG. 8 is a perspective view of the brace structure of the system of FIG. 5 with the upper lamination of the brace structure and confocal imaging head removed;

20 FIG. 9 is a perspective view of the system in accordance with a third embodiment of the present invention;

FIG. 10 is a cross-sectional view of the system along line 10-10 of FIG. 9 when the attachment of the system is not engaging skin tissue; and

FIG. 11 is another cross-sectional view of the system along line 10-10 of FIG. 9 when the attachment of the system is engaging skin tissue.

Detailed Description of the Invention

Referring to FIGS. 1-4, there is shown system 14 including a rigid table 16 with a pad 17 on table surface 16a upon which a patient 18 may lay flat. Pad 17 may be composed of a vinyl-covered cell foam (such as CF 40100 Foam from EAR Specialty Composites of Indianapolis, Indiana) which deforms under the weight of patient 18 and remains deformed for a period of time after the patient has left the table. Table 16 has two parallel rails 20 spaced apart from each other along two opposite sides of table 16, and two parallel rails 22 spaced apart from each other. Rails 20 and 22 are perpendicular to each other, i.e., rails 20 extend in the x direction and rails 22 extend in the y direction.

A platen 30 carrying a confocal imaging head 34 is mounted in a mechanism provided by rails 20 and 22 for movably positioning head 34 to observe dermal tissue of interest in the body of patient 18. This mechanism has a carriage 25 supporting platen 30. Carriage 25 rides along rails 22 across table 16 (as indicated by bidirectional arrow x), and is locked in position with respect to rails 22 by a lock 28, such as a locking screw. Rails 22 and its two spacers 23, which connect rails 22 together, ride along rails 20 up or down table 16 (as indicated by bi-directional arrow y), and are locked in position with respect to rails 20 by a lock 24, such as a locking screw. Thus, platen 30 can then be moved by the operator in two orthogonal directions x and y over patient 18 and temporarily fixed in a desired position.

Referring to FIG. 4, platen 30 and the head 34 assembly is shown in more detail.

Platen 30 is a rigid structure having an upper surface 31 with a translation stage 36 which is mechanically coupled to a confocal imaging head 34 via support 36a. Confocal imaging head 34 has an objective lens 35 positioned over an orifice or opening 32 through platen 30. Confocal imaging head 34 with objective lens 35 are described in U.S. Application No. 08/650,684, filed 5/20/96 and assigned to the same assignee as the present invention, and is herein incorporated by reference. Translation stage 36 is movable in two orthogonal directions x' and y' (see arrows x' and y' in FIG. 4) to provide fine resolution positioning (as compared with coarse positioning of platen 30 via rails 20 and 22) of imaging head 34, and

more specifically objective lens 35, with respect to platen 30 over orifice 32. The translation stage 36 has cross rotating ball bearings (not shown) or cross piezoelectric position actuators to facilitate fine resolution movement in orthogonal directions x' and y' . Manual stage micrometers 37a and 37b adjust translation stage 36 in x' and y' directions, respectively.

5 Micrometers 37a and 37b may be substituted by motors which are remotely controlled. A lock (not shown) on translation stage 36 may be provided to temporarily fix the position of stage 30, and consequently imaging head 22, with respect to platen 30. Thus, translation stage 36 defines a means for fine resolution positioning of the objective lens over the orifice. Also, an index matching plate 38 may be positioned within orifice 32 in front of objective lens 35 to
10 form a window which maintains the height stability of the tissue while presenting the edges of orifice 32 to the skin for stressing the tissue.

Platen 30 includes four vibration damping rods 40 at the four corners of platen 30 (for purposes of illustration only two rods 40 are shown in FIG. 4). Each damping rod 40 has a lower end coupled to platen 30 and an upper end coupled to carriage 25, as shown in FIGS.
15 1-3. Thus, damping rods 40 connect platen 30 to carriage 25. Damping rods 40 may be hydraulic type shock absorbers which when released allow platen 30 to gradually move from an up position to a down position upon the patient's skin 14a (such as shown in FIG. 1) and also allow platen 30 to be moved from a down position back to an up position. Locking screws (not shown) on the damping rods 40 may fix the position of platen 30 with respect to
20 carriage 25 in either up or down positions. Damping rods 40 thereby provide a means for moving platen 30 from an up position, in which the platen is spaced from patient 18, to a down position onto surface 18a of skin tissue of the patient.

In operation of system 14, the operator (e.g., a physician) moves rails 22 (i.e., the rails upon which carriage 25 rides) along rails 20 to position platen 30 in the y direction, and
25 moves carriage 25 along rails 22 to position platen 30 in the x -direction such that the volume of skin tissue of interest on patient 18, such as a lesion, will be positioned within orifice 23 of the platen when platen 30 is in a down position. Using locks 24 and 28 described above, the

operator locks carriage 25 with respect to rails 20 and 22, thus fixing the position of platen 30 with respect to patient 18. Next, the operator releases damping rods 40 to allow platen 30 to gradually fall by the force of gravity onto the patient's skin. In response to the weight of platen 30, the skin lying within orifice 32 of platen 30 bulges upwards into orifice 32, thereby applying stress to the skin. This stress places the skin in orifice 32 preferably under tension, but may further push the skin up into orifice 32 by compression of skin beneath platen 30. The stress applied to the skin in orifice 32 is substantially due to the downward pressure or force of platen 30 at the edges of orifice 32. Optionally, springs may be located within damping rods 40 to provide additional downward pressure onto the skin. The operator then controls the translation stage movement either directly or remotely to position objective lens 35 of imaging head 34 over area of tissue within orifice 32 desired to be imaged. The operator enables optics within the confocal imaging head to confocally image horizontal, vertical, or angular sections through different planes of the tissue. During confocal imaging, the stress applied to the skin tissue in orifice 32 stabilize the tissue reducing motion of the skin tissue with respect to confocal imaging head 34, thereby stabilizing confocal images scanned by head 34.

Platen 30 may have a paper pad 42 to provide a recording media, and a pen or marker 44 mechanically coupled to translation stage 36 by arm 43 such that pen 44 is suspended over pad 42. Movement of translation stage 36 can thus be recorded by ink from the pen 44 on pad 32. This allows the operator during confocal imaging by imaging head 34 to map the horizontal extent or borders of a lesion in the skin, since pen 44 transfers the motion of translation stage 36 on pad 43 by the fixed geometry which mechanically couples pen 44 to objective lens 23 via arm 43, stage 36, support 36a and imaging head 34. After confocal imaging is complete, imaging head 34 may be replaced by another pen to permit the operator to trace the extent of the lesion recorded on pad 32 onto the surface of the skin.

Further, when platen 30 is in a down position, the operator can place index marks on the skin surface with a pen, or other marking instrument, at notches (not shown) along the

sides of orifice 32. These index marks locate both orifice 32 and the relative position of objective lens 35 with respect to the skin surface when confocal imaging is performed. In subsequent examinations, orifice 32 and objective lens 35 can be aligned with these index marks to confocally image the same area of skin, and, for example, observe changes occurring in a skin lesion over time.

A second embodiment of the present invention is shown in FIGS. 5-8 having a system 58. System 58 includes a brace structure 50 having a rigid lower lamination 52 which is held stationary to the skin tissue 18a of patient 18 by straps 54. Lower lamination 52 is shaped to approximate the curvature of a gross anatomical body part of the patient, such as part of the leg, torso, or arm, as shown in FIG. 5. A bottom 52a of lower lamination 52 has an opening 53, as shown in FIGS. 7 and 8. Bottom 52a defines a well 59 therein between ends 57a and sides 57b of lower lamination 52. Ends 57a and sides 57b define a rigid frame 57. Further, ends 57a and sides 57b have blind slots 55 within which an upper lamination 56 is captured. FIG. 8 shows frame 57 of lower lamination 52 in which upper lamination 56 has been removed for purposes of illustration.

Upper lamination 56 is a curved rigid sheet parallel with lower lamination 52, and has a confocal viewing window 58 (FIG. 7) substantially smaller than opening 53. Viewing window 58 may be positioned at a location over opening 53 by sliding upper lamination 56 over lower lamination 52 via slots 55 within frame 57. A confocal imaging head 60 is supported on brace structure 50 by gussets 62 (FIG. 6) and has an objective lens (not shown) positioned for imaging through confocal viewing window 58 of upper lamination 56. The window may contain a transparent plate for tissue height stabilization. Confocal imaging head 60 with objective lens 35 are described in U.S. Application No. 08/650,684, filed 5/20/96 and assigned to the same assignee as the present invention, and is herein incorporated by reference. Confocal imaging head 60 is fixably attached to upper lamination 56 and slides therewith over lower lamination 52.

In operation of system 58, brace 50 is first strapped by straps 54 over an anatomical feature, such as an arm, leg, or torso, in which the general skin tissue area to be confocally imaged bulges upward through opening 53 of bottom 52a under the pressure from lower lamination 52, thereby applying stress to the surface of the skin. This stress preferably places the skin through opening 53 under tension, but may further push the skin up into opening 53 by compression of skin beneath lower lamination 52. The stress applied to the skin in opening 53 is substantially due to the pressure or force from lower lamination 52 to the skin tissue at the edges of opening 53. The specific area of the skin to be confocally imaged is then positioned within confocal viewing window 58 by sliding upper lamination 56 over lower lamination 52. Lower lamination 52 provides a sliding surface for upper lamination 56 and slots 55 of frame 57 provide sufficient friction against upper lamination 56 to temporarily fix the position of upper lamination 56 with respect to lower lamination 52 and the skin tissue. Confocal imaging head 60 is then attached to upper lamination 56 of brace 50 to position the confocal optics of head 60, i.e., its objective lens, through confocal imaging window 58. When enabled, these confocal optics within imaging head 60 can confocally image horizontal, vertical, or angular sections through different planes of the tissue through confocal viewing window 58. Thus, brace 50 locates confocal imaging head 60 in fixed relationship with the skin tissue, and window 58 defines an aperture through brace 50 for imaging via optics of head 60.

By attaching imaging head 60 to upper lamination 56, head 60 moves with motion of the skin tissue since such motion is transferred to head 60 via brace structure 50. This reduces the relative motion of the tissue held under stress with respect to the confocal optics of imaging head 60 to minimize instability of the confocal images from imaging head 60. Upper lamination 56 may be moved to reposition the confocal imaging optics of head 60 through window 58 for confocal imaging of other areas of skin tissue within opening 53.

A third embodiment of the present invention is shown in FIGS. 9-11. This embodiment is provided by a tissue stabilization system 68 which includes an attachment 69.

The tissue is shown at 84 in FIGS. 10-11 as a layer of skin. Attachment 69 includes a flexible diaphragm member 70, a central circular window or plate member 72, and a semi-rigid ring 74. Diaphragm 70 is composed of deformable rubber selected to be less compliant than tissue 84. Diaphragm 70 radially extends from window 72 outward to semi-rigid ring 74. Ring 74 may be composed of hard rubber, while window 72 may be composed of a material having an optical index approximately matching tissue 84. Diaphragm 70 has between ring 74 and window 72 an annular protruding section 75 (protruding in the direction of the arrow of FIG. 10). Section 75 defines outer and inner annular cavities 76 and 78, respectively. Also, attachment 69 has a pair of vacuum lines 80 which each connects different ones of annular cavities 76 and 78 to a pneumatic pump which selectively creates suction between diaphragm 70 and the surface 84a of tissue 84. The size or diameter of system 68 and its attachment 69 may be appropriately dimensioned for the skin surface area to be confocally imaged through window 72.

System 68 further includes a confocal imaging head 82 having an objective lens 83 positioned such that lens 83 is directed to window 72 of attachment 69. Confocal imaging head 60 with objective lens 35 are described in U.S. Application No. 08/650,684, filed May 20, 1996 and assigned to the same assignee as the present invention, and is herein incorporated by reference. Objective lens 83 is shown in phantom lines in FIG. 9, and the dotted lines in the figure represent the optical imaging paths between lens 83 and other confocal optics within imaging head 82. For example, these optical imaging paths may be provided within an extending snout between head 82 and objective lens 83.

In operation, attachment 69 is first placed over surface 84a of tissue 84 such that diaphragm protruding section 75 is adjacent to surface 84a, as shown in FIG. 10. When window 72 is located over the area of tissue 84 to be confocally imaged, the air is evacuated via vacuum lines 80 from each cavity 76 and 78. This creates suction which pulls tissue 84 up into cavities 76 and 78, as shown in FIG. 11. As a result, semi-rigid ring 74 and window 72 are pulled downward onto surface 84, and the tissue beneath window 72 is placed under stress,

such as by tension or compression. In this mode, attachment 69 engages or adheres by suction to the surface 84a of the tissue.

Next, objective lens 83 of confocal imaging head 82 is placed against window 72 for confocal imaging of tissue 84 below window 72, then the confocal optics within imaging head 60 are enabled to provide confocal images of horizontal, vertical and angular sections through different planes of the tissue. Optionally, attachment 69 may be fixedly attached to head 82 in front of its objective lens 83 prior to placing attachment 69 adjacent to the skin tissue. Since the tissue being confocally imaged is held under stress by attachment 69 under window 72, the relative motion of this tissue with respect to the confocal optics within imaging head 82 is reduced, thereby stabilizing confocal images from head 82. When imaging is complete, air is allowed to flow back into cavities 76 and 78 via vacuum lines 80, allowing attachment 69 to disengage from the surface 84a of the tissue.

Alternatively, a liquid on the surface 84a of the tissue may be evacuated via vacuum lines 80 (in combination with or instead of air) from cavities 76 and 78. Such a liquid may be applied to the surface 84a of the tissue prior to placing attachment 69 over the surface.

Each of the three embodiments of the present invention is particularly suitable for imaging external tissue in different regions of the patient's body. The first embodiment may be used for confocal imaging of skin tissue on the chest or back, while the second embodiment may be used for gross anatomical features, such as the arm or leg, around which straps can hold brace structure 50 upon. Further, the third embodiment is useful for smaller regions of the skin, particularly where there is no gross anatomical feature, or where the surface of the skin tissue is not substantially level, such as the cervix or forehead. Each of the above confocal imaging system embodiments provides a mechanism for maintaining an area of skin tissue being confocal imaged under a stressed configuration by tension or compression, thereby minimizing the motion of this area with respect to a confocal imaging head. In the cervix the tissue being imaged is not skin as that term is commonly understood, but represents

internal tissue of a patient. Internal tissues, for example which are surgically exposed, may be stabilized using the invention.

From the foregoing description, it will be apparent that there have been provided several embodiments of a confocal imaging system for dermatological pathology applications.

5 Variations and modifications of the herein described system and other applications for the invention will undoubtedly suggest themselves to those skilled in the art. Accordingly, the foregoing description should be taken as illustrative and not in a limiting sense.

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What is claimed is:

1. A system for dermatological examination of the skin tissue of a patient comprising:

means for maintaining an area of the skin tissue under stress by application of force at the edges of said area; and

an imaging head coupled to said means for imaging said stressed skin to provide therewith an integrated assembly.

2. The system according to Claim 1 wherein said maintaining means further comprises:

a platen which is positionable with respect to said patient, said platen having an orifice, and said imaging head being coupled to said platen and positioned for imaging through said orifice; and

first means for moving said platen from an up position in which said platen is spaced from said patient to a down position onto the surface of said skin tissue of the patient, whereby in said down position the force of said platen provides said stressed skin tissue within said orifice.

3. The system according to Claim 2 wherein said maintaining means further comprises:

second means coupled to said platen for moving said platen with respect to said patient and temporarily fixing the position of said platen so that said skin tissue to be imaged is located within said orifice when said first means moves said platen to said down position.

4. The system according to Claim 3 wherein said second means further comprises: a table having a surface supporting said patient and two opposing sides spaced apart from each other on opposite sides of said patient;

two first rails, each of said first rails being parallel to each other and located upon a different one of said opposing sides;

two second rails orthogonal to said first rails which are parallel to each other and movable together along said first rails;

5 a carriage supporting said platen which is movable along said second rails;
means for locking said second rails at a position with respect to said first rails;
and
means for locking said carriage at a position with respect to said second rails.

10 5. The system according to Claim 4 wherein said first means comprises a plurality of rods coupling said platen to said carriage for positioning said platen in one of said up and down positions.

15 6. The system according to Claim 2 wherein said maintaining means further comprises:
means coupled to said imaging head and said platen for translating said imaging head with respect to said orifice of said platen.

20 7. The system according to Claim 6 wherein said platen further comprises a recording media, and said translating mean further comprises a translation stage and a marker coupled to said translation stage which is positioned over said media to record the motion of said translating stage as it moves said imaging head over said stressed tissue within said orifice.

25 8. The system according to Claim 2 wherein said orifice has a plate positioned therein.

9. The system according to Claim 1 said maintaining means further comprises:

a brace supporting said imaging head which comprises an opening in said brace through which said imaging head images said skin tissue, and means for restraining said brace to the body part of the patient having said skin tissue to force said brace against said skin tissue and provide within said opening of said brace said stressed skin tissue.

10. The system according to Claim 9 wherein said brace further comprises an upper lamination coupled to said imaging head, and a lower lamination coupled to said restraining means, said lower lamination having said opening and slots for receiving said upper lamination in which said upper lamination is movable within said slots over said lower lamination and temporarily fixable within respect to said lower lamination, said upper lamination having an aperture substantially smaller than said opening of said lower lamination through which said imaging head images said stressed skin tissue within said opening of said lower lamination.

11. The system according to Claim 10 wherein said lower lamination comprises a surface which approximates the surface of the skin tissue, and said upper lamination comprises a rigid member parallel with said lower lamination.

12. The system according to Claim 10 wherein said aperture has a transparent plate positioned therein.

13. The system according to Claim 1 wherein said maintaining means further comprises:

an attachment having an inner member and a flexible outer member extending radially from said inner member; and

means for creating a vacuum between said attachment and the surface of said skin tissue, to force said skin tissue against said inner member and provide adjacent to said

inner member said stressed tissue, in which said imaging head images said stressed skin tissue through said inner member.

14. The system according to Claim 13 wherein said outer member has a semi-rigid ring along its outer periphery, and an annular protruding section which defines inner and outer cavities when said attachment is adjacent to said skin tissue.

15. The system according to Claim 14 wherein said vacuum suctioning means further comprises means for selectively creating suction in said inner and outer cavities when said attachment is adjacent to said skin tissue to pull said skin tissue into said cavities, thereby applying stress to the skin tissue adjacent to said inner member.

16. The system according to Claim 13 wherein said first member is a circular window having an optical index approximately matching said skin tissue.

17. The system according to Claim 13 wherein said second member is a deformable diaphragm which is less compliant than said skin tissue.

18. The system according to Claim 13 wherein said vacuum suctioning means further comprises means for suctioning air or a liquid, applied to the surface of said skin tissue, between said attachment and said skin tissue.

19. The system according to Claim 1 wherein said imaging head is a confocal imaging head having confocal imaging optics for providing images of sections of said stressed skin tissue.

20. An apparatus for stabilizing the skin tissue of a patient to an imaging head comprising:

a platen having an orifice;

first means for moving said platen from an up position in which said platen is spaced from said patient to a down position onto the surface of said skin tissue of the patient; and

second means for moving said platen over the patient and temporarily fixing the position of the platen with respect to said patient wherein the skin tissue to be imaged by said imaging head is stabilized within said orifice when said platen is in a down position.

21. The system according to Claim 20 wherein said second means further comprises:

a table having a surface supporting said patient and two opposing sides spaced apart from each other on opposite sides of said patient;

two first rails, each of said first rails being parallel to each other and located upon a different one of said opposing sides;

two second rails orthogonal to said first rails which are parallel to each other and movable together along said first rails;

a carriage supporting said platen which is movable along said second rails;

means for locking said second rails at a position with respect to said first rails;

and

means for locking said carriage at a position with respect to said second rails.

22. The system according to Claim 21 wherein said first means comprises a plurality of rods coupling said platen to said carriage for positioning said platen in one of said up and down positions.

23. The system according to Claim 20 wherein said maintaining means further comprises:

means coupled to said imaging head and said platen for translating said imaging head with respect to said orifice of said platen.

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24. An apparatus for stabilizing the skin tissue of a patient to an imaging head comprising:

a structure providing a brace and having straps which attaches said brace structure to the surface of the skin tissue, a lower lamination comprising a surface which approximates the surface of the skin tissue, and an upper lamination over said lower lamination having a surface with an opening defining a viewing window; and

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said lower lamination further comprising slots in which said upper lamination is received, and an opening through which said skin tissue to be imaged by said imaging head is located, wherein said upper lamination is slidable over said surface of said lower lamination within said slots. and said upper lamination is attachable to said imaging head for imaging said skin tissue through said viewing window and through said opening of said lower lamination to stabilize said skin tissue in said opening to said imaging head.

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25. An apparatus for stabilizing the tissue of a patient to an imaging head comprising:

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an attachment having a central circular window plate, a deformable diaphragm and a semi-rigid ring, wherein said diaphragm radially extends outward from said window plate to said semi-rigid ring;

said diaphragm having an annular protruding section which defines inner and outer cavities when said attachment is adjacent to the surface of said tissue; and

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means for selectively creating suction in said inner and outer cavities when said attachment is adjacent to said the surface of said tissue to pull said tissue into said cavities, thereby stabilizing said tissue adjacent to said window plate for imaging by said imaging head.

- 5 26. A system for examining the tissue of a patient comprising:
 means for maintaining an area of the tissue under stress by application of force
 at the edges of said area; and
 an imaging head coupled to said means for imaging said stressed tissue to
10 provide therewith an integrated assembly.

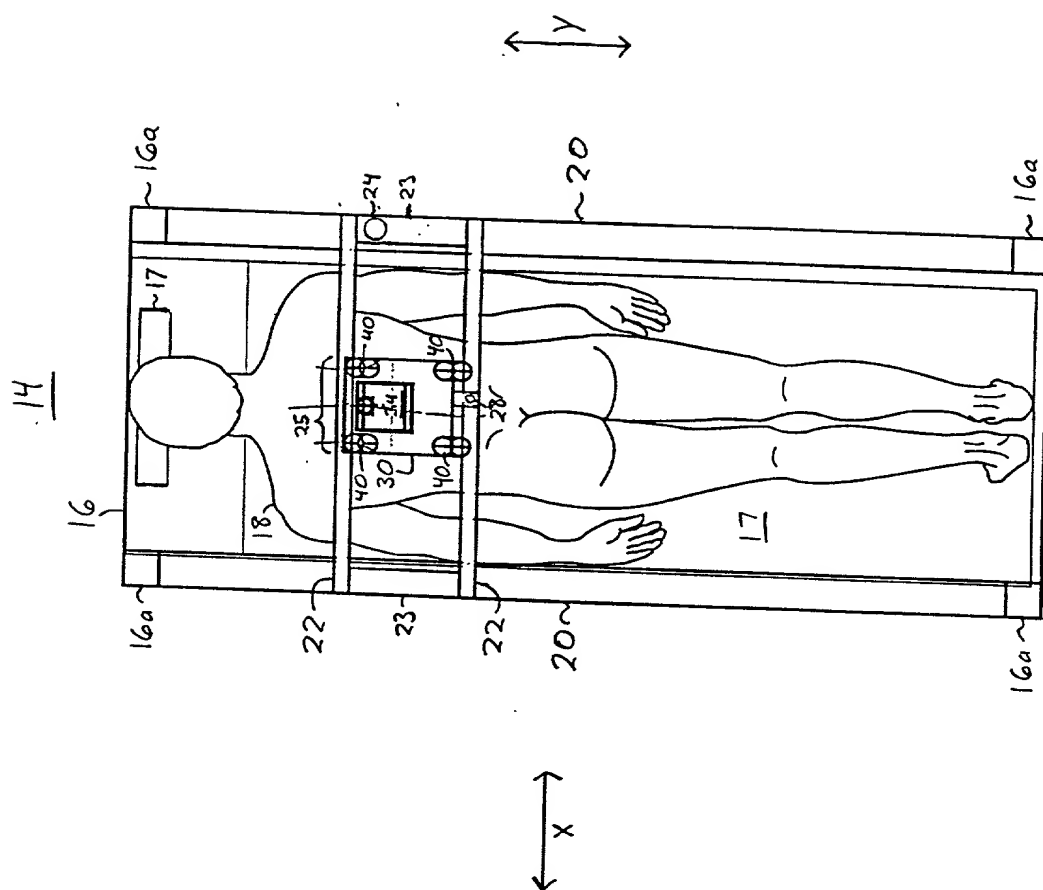


Fig. 2

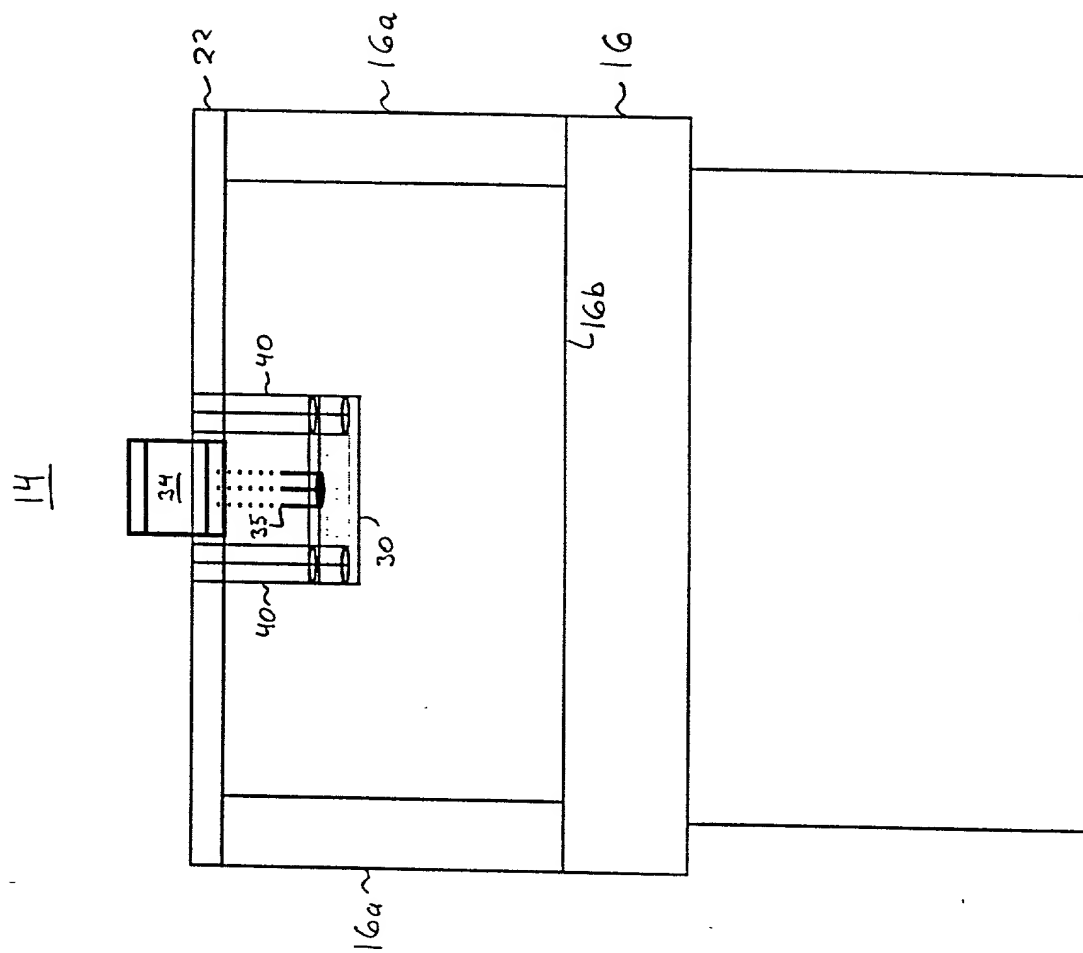


FIG. 3

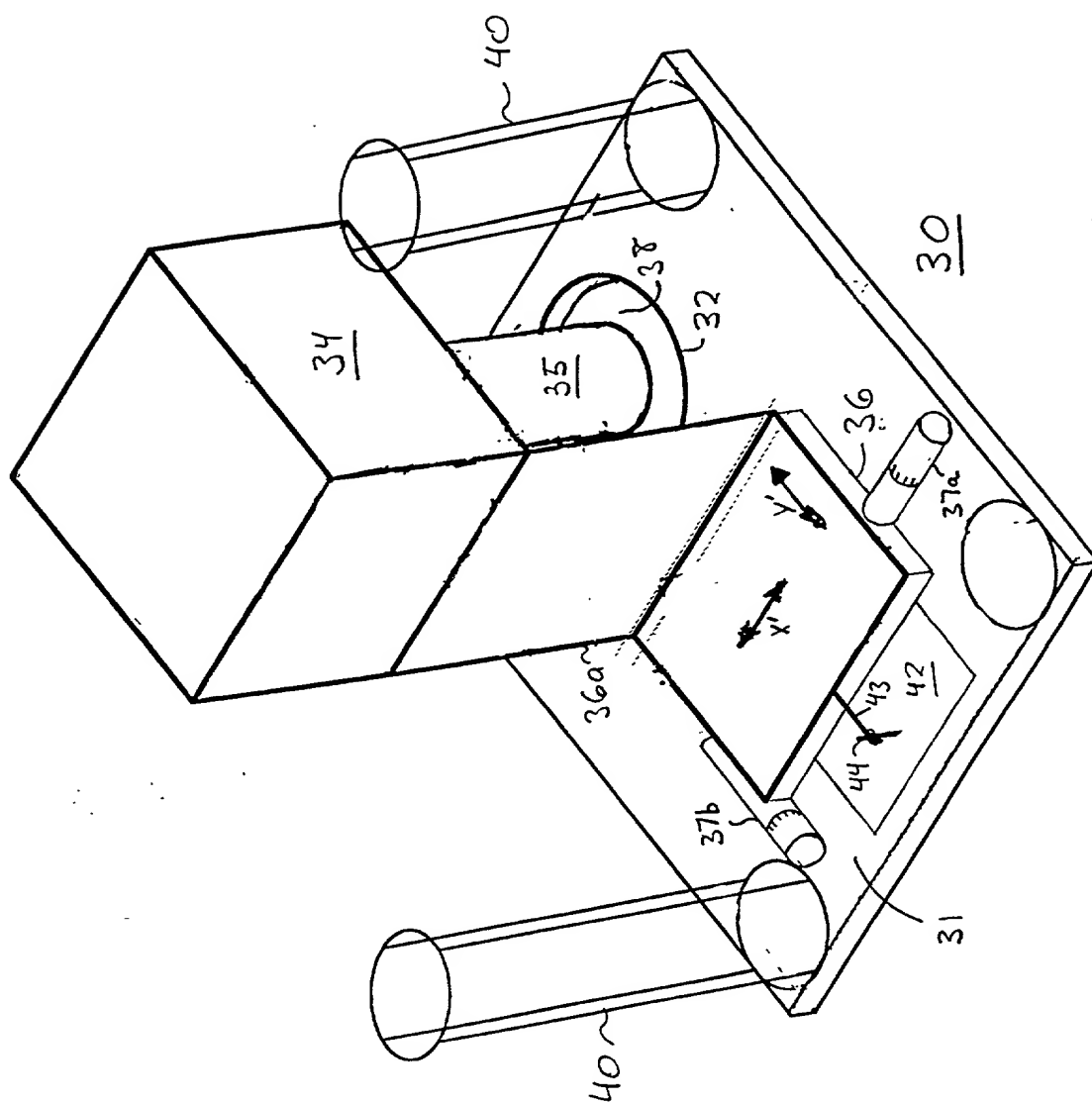


Fig. 1

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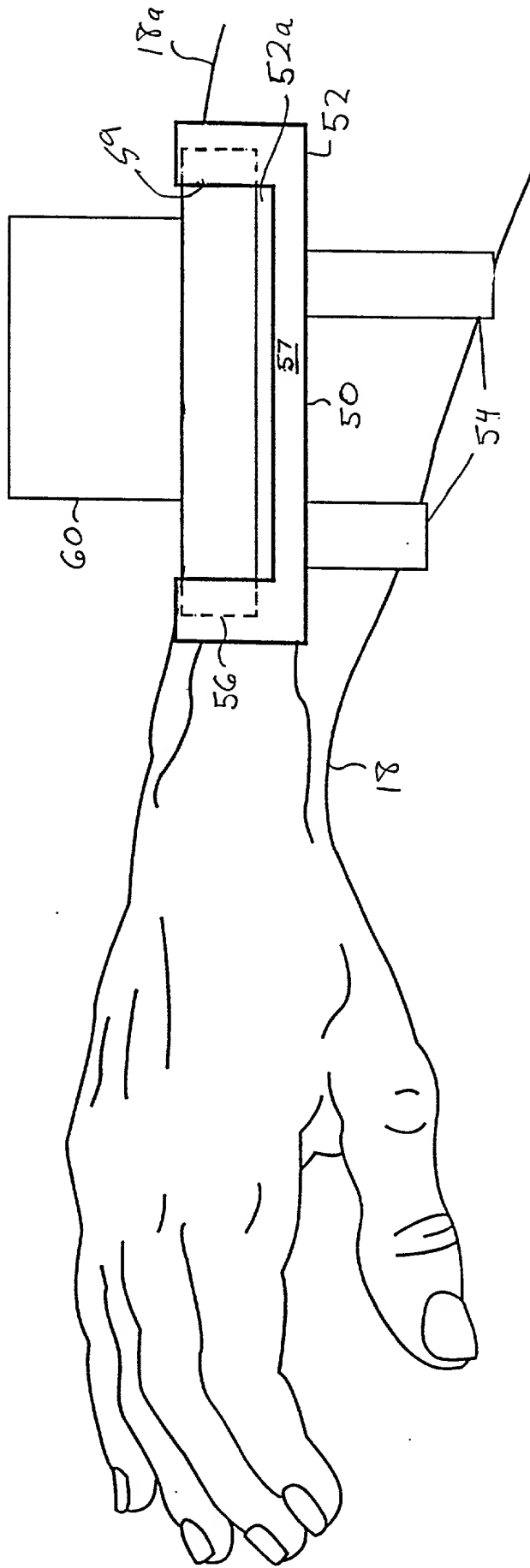


FIG. 5

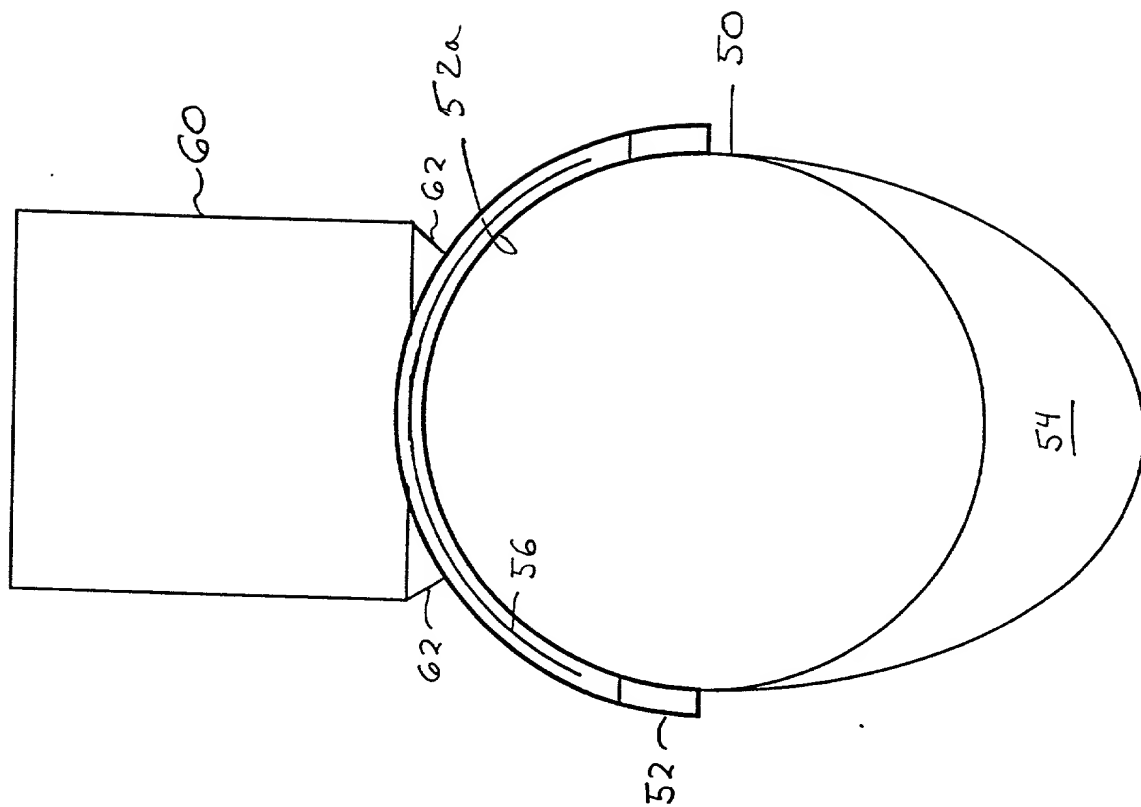


FIG. 6

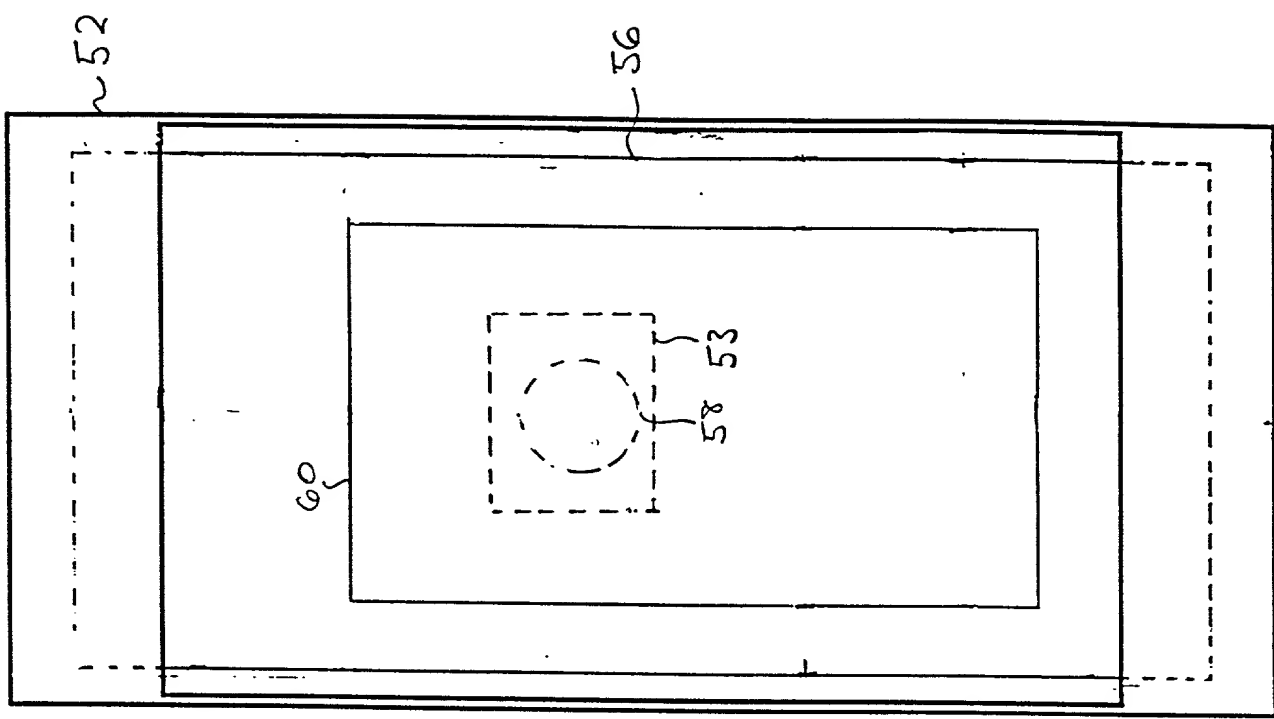


FIG. 7

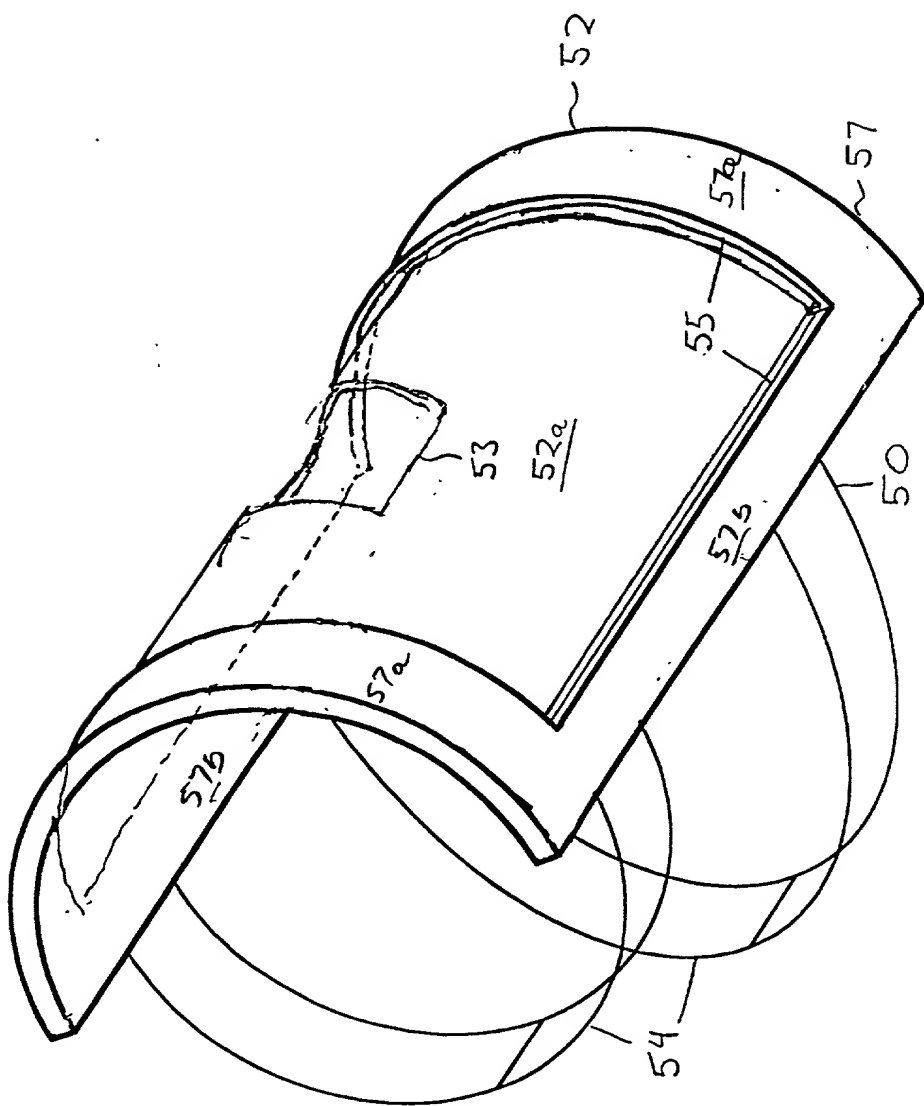


FIG. 8

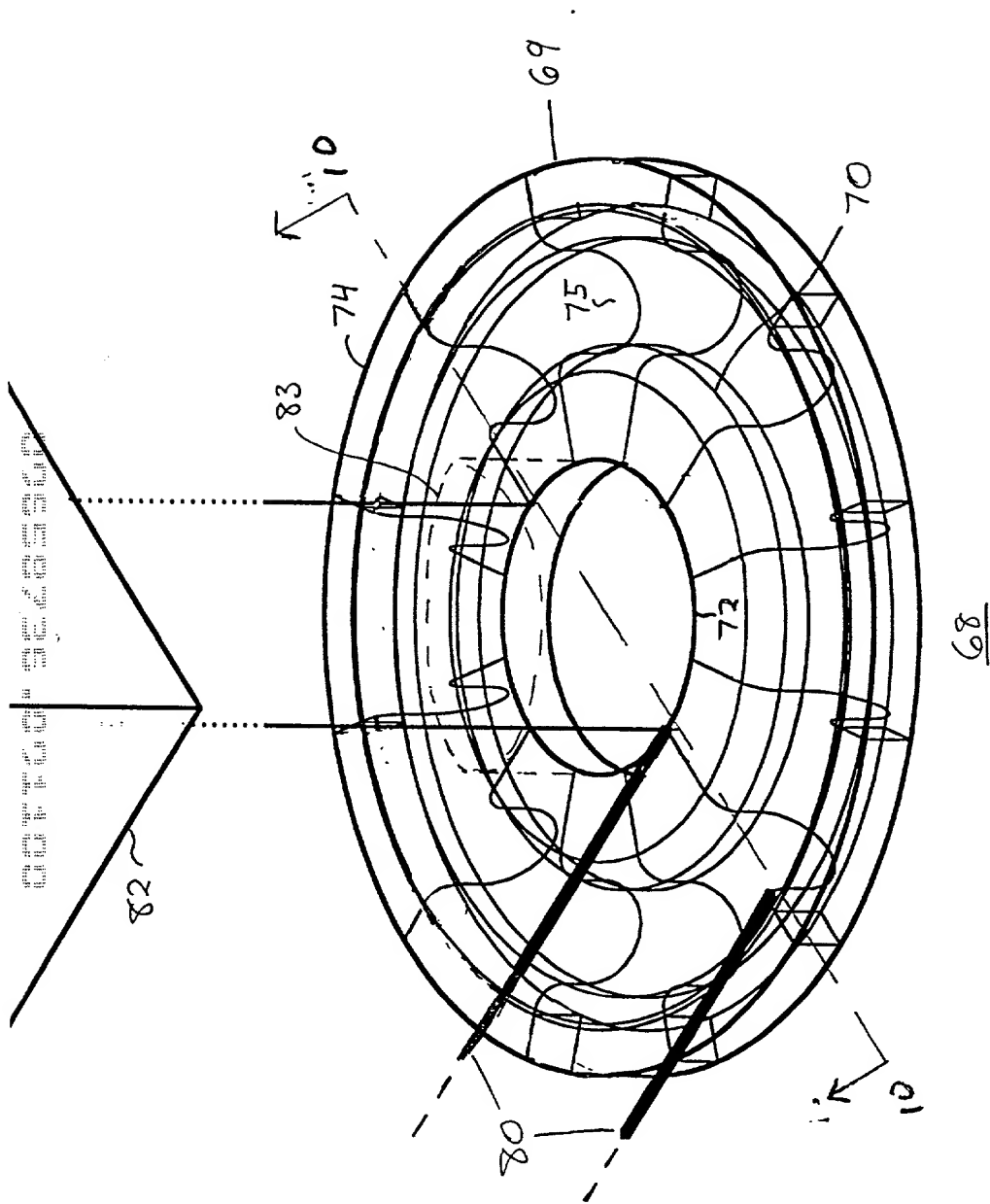


FIG. 9

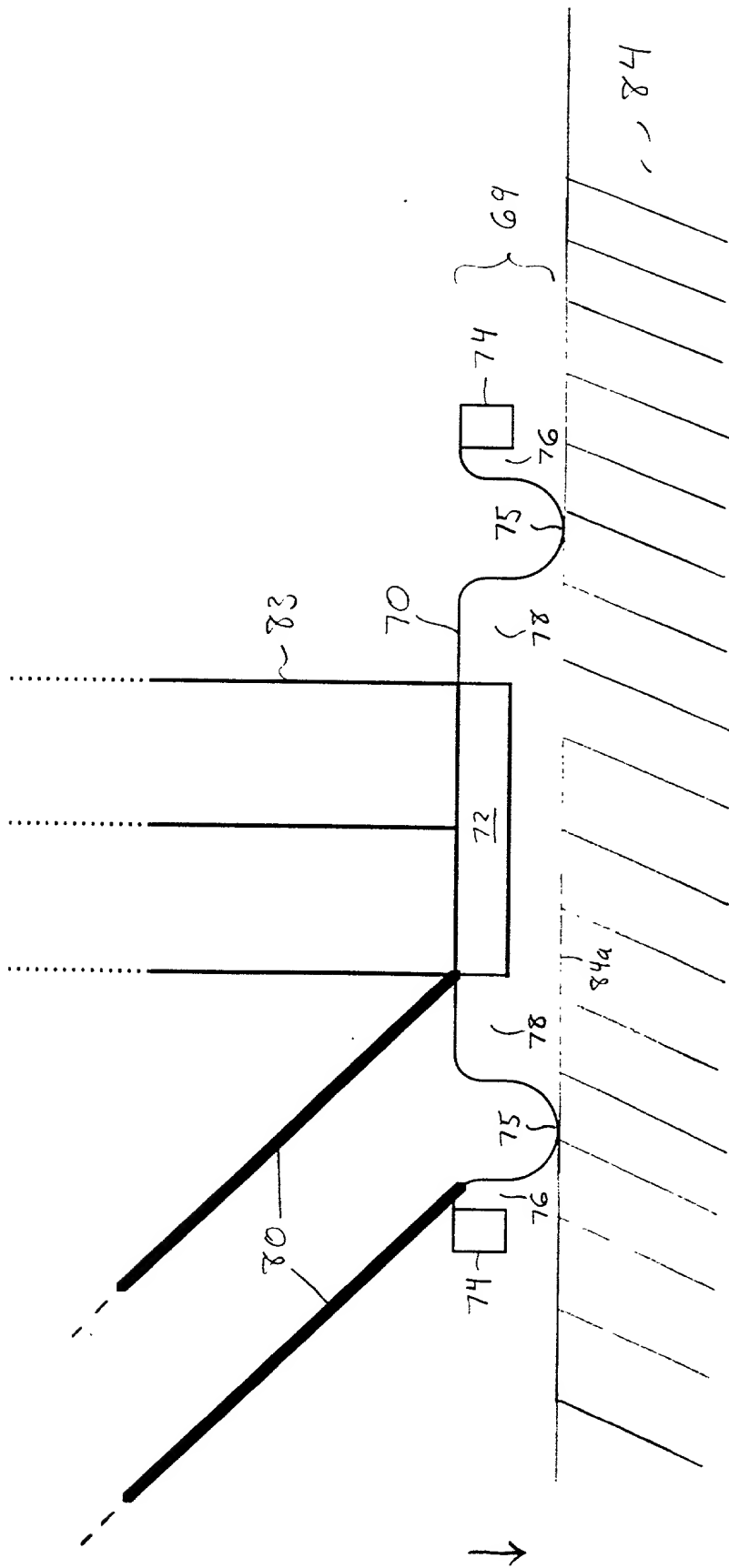


FIG. 10

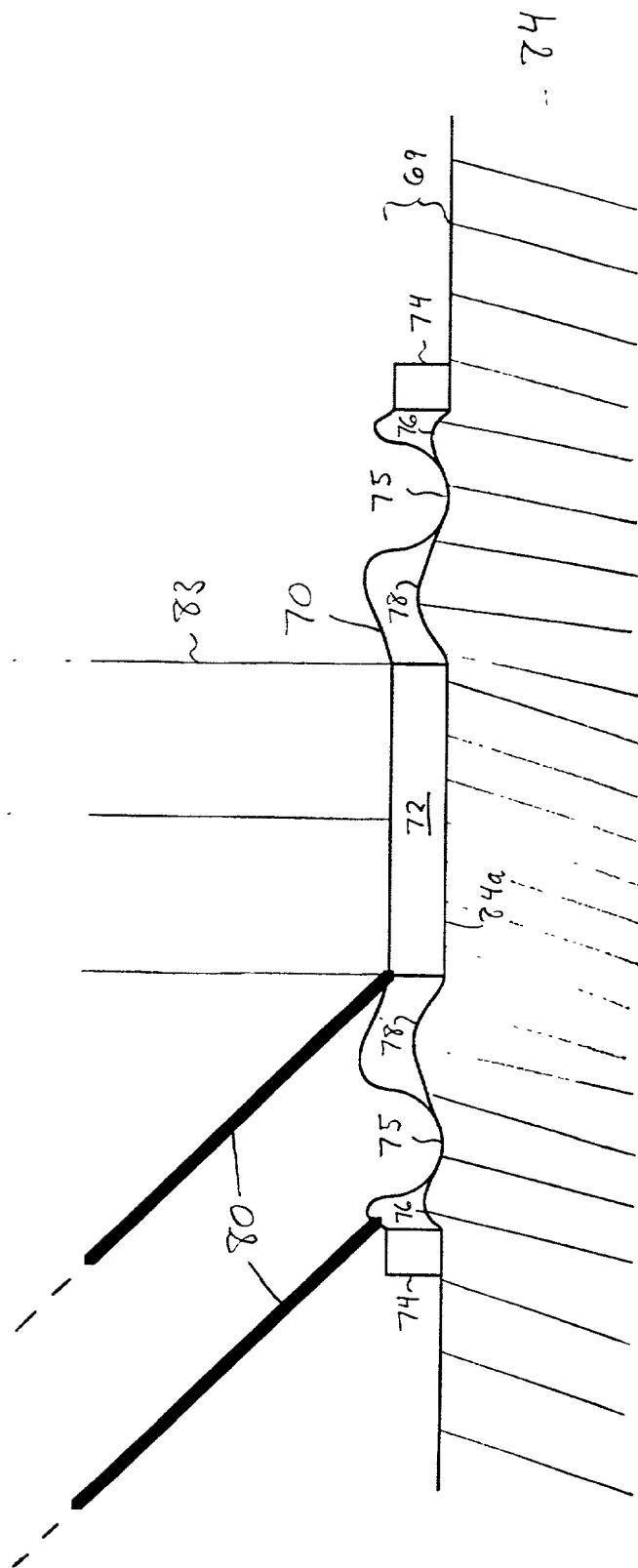


FIG. 11

Docket No.

ML-0414CV

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

SYSTEM FOR CONFOCAL IMAGING WITHIN DERMAL TISSUE

the specification of which

(check one)

☒ is attached hereto.

☐ was filed on _____ as United States Application No. or PCT International

Application Number _____

and was amended on _____

(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Priority Not Claimed

_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/>
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/>
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/>

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

60/028,847

10/18/96

(Application Serial No.)

(Filing Date)

(Application Serial No.)

(Filing Date)

(Application Serial No.)

(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112. I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

(Application Serial No.)

(Filing Date)

(Status)
(patented, pending, abandoned)

(Application Serial No.)

(Filing Date)

(Status)
(patented, pending, abandoned)

(Application Serial No.)

(Filing Date)

(Status)
(patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

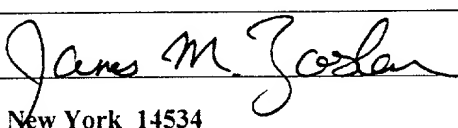
POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(list name and registration number)*

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Second inventor's signature	Date
Residence	
Citizenship	
Post Office Address	